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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH US, LLC f/k/a VALEANT
PHARMACEUTICALS NORTH AMERICA
LLC; BAUSCH HEALTH IRELAND LIMITED
f/k/a VALEANT PHARMACEUTICALS
IRELAND LTD.; BAUSCH HEALTH
AMERICAS, INC. f/k/a VALEANT
PHARMACEUTICALS INTERNATIONAL;
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No. 20-2737

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health US, LLC (“Bausch,” formerly known as Valeant Pharmaceuticals North America LLC), Bausch Pharmaceuticals Ireland Ltd. (“Bausch Ireland,” formerly known as Valeant Pharmaceuticals Ireland Ltd.), and Bausch Health Americas, Inc. (“Bausch Americas,” formerly known as Valeant Pharmaceuticals International), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Alkem Laboratories Ltd. (“Alkem”) allege as follows:

THE PARTIES

1. Plaintiff Bausch is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Bausch Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware, having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Alkem is an Indian corporation having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai – 400 013, India.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 10,512,640 (“the ’640 patent”); 10,342,875 (“the ’875 patent”); and 10,478,601 (“the ’601 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Alkem’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its

generic efinaconazole topical solution, 10% (“Alkem’s generic efinaconazole topical solution”).¹

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201–02.

8. Upon information and belief, this court has jurisdiction over Alkem. Upon information and belief, Alkem is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Alkem directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Alkem’s generic efinaconazole topical solution. Upon information and belief, Alkem has a wholly-owned subsidiary located in New Jersey. Upon information and belief, Alkem purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Alkem has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction, including actions related to the same ANDA at issue in this suit.

9. Alkem has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Alkem’s ANDA filings constitute formal acts that reliably indicate plans to engage in marketing

¹ A related action against Alkem for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”), 9,877,955 (“the ’955 patent”), and 10,105,444 (“the ’444 patent”) is pending in this District. See Nos. 3:18-cv-13905, 3:18-cv-17731 (consolidated into No. 3:18-cv-13635).

of the proposed generic drugs. Upon information and belief, Alkem intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Alkem will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

10. Alkem knows or should know that Jublia® is manufactured for Bausch, formerly known as Valeant Pharmaceuticals North America LLC, in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Jublia®.

11. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

12. Venue is proper against Alkem, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENTS IN SUIT

13. The United States Patent and Trademark Office (“PTO”) issued the ’640 patent on December 24, 2019. The ’640 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and a triazole antifungal agent. Plaintiffs hold all substantial rights in the ’640 patent and have the right to sue for infringement thereof. The ’640 patent is valid and enforceable. A copy of the ’640 patent is attached hereto as Exhibit A.

14. The PTO issued the ’875 patent on July 9, 2019. The ’875 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate, butylated hydroxytoluene (BHT), a salt of ethylenediaminetetraacetic acid

(EDTA), citric acid and a triazole antifungal agent. Plaintiffs hold all substantial rights in the '875 patent and have the right to sue for infringement thereof. The '875 patent is valid and enforceable. A copy of the '875 patent is attached hereto as Exhibit B.

15. The PTO issued the '601 patent on November 19, 2019. The '601 patent claims, generally speaking, *inter alia*, drug applicators with specific physical characteristics, and methods of using said applicators to treat, among other diseases, tinea unguium (onychomycosis). Plaintiffs hold all substantial rights in the '601 patent and have the right to sue for infringement thereof. The '601 patent is valid and enforceable. A copy of the '601 patent is attached hereto as Exhibit C.

16. Bausch Americas is the holder of New Drug Application ("NDA") No. 203567 for Jublia®, which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '640, '875 and '601 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

17. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia®.

ALKEM'S INFRINGING ANDA SUBMISSION

18. Upon information and belief, Alkem filed or caused to be filed with the FDA ANDA No. 212195, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

19. Upon information and belief, Alkem's ANDA No. 212195 seeks FDA approval to sell in the United States Alkem's generic efinaconazole topical solution, intended to be a generic version of Jublia®.

20. Upon information and belief, ANDA No. 212195 seeks approval of Alkem's generic efinaconazole topical solution that is the same, or substantially the same, as Jublia®.

COUNT I AGAINST ALKEM

Infringement of the '640 Patent under § 271(e)(2)

21. Paragraphs 1–20 are incorporated herein as set forth above.
22. Under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '640 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '640 patent.
23. Upon information and belief, Alkem's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '640 patent.
24. Upon information and belief, Alkem will, through the manufacture, use, import, offer for sale, and/or sale of Alkem's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.
25. If Alkem's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '640 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST ALKEM

Declaratory Judgment of Infringement of the '640 Patent

26. Paragraphs 1–25 are incorporated herein as set forth above.
27. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
28. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States

Constitution, and this actual case or controversy requires a declaration of rights by this Court.

29. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '640 patent, including Alkem's filing of ANDA No. 212195.

30. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.

31. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will constitute infringement of at least one claim of the '640 patent.

COUNT III AGAINST ALKEM

Infringement of the '875 Patent under § 271(e)(2)

32. Paragraphs 1–31 are incorporated herein as set forth above.

33. Under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '875 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '875 patent.

34. Upon information and belief, Alkem's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '875 patent.

35. Upon information and belief, Alkem will, through the manufacture, use, import, offer for sale, and/or sale of Alkem's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

36. If Alkem's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '875 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV AGAINST ALKEM

Declaratory Judgment of Infringement of the '875 Patent

37. Paragraphs 1–36 are incorporated herein as set forth above.

38. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

40. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '875 patent, including Alkem's filing of ANDA No. 212195.

41. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

42. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will constitute infringement of at least one claim of the '875 patent.

COUNT V AGAINST ALKEM

Infringement of the '601 Patent under § 271(e)(2)

43. Paragraphs 1–42 are incorporated herein as set forth above.
44. Under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '601 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212195 seeking approval for the commercial marketing of Alkem's generic efinaconazole topical solution before the expiration date of the '601 patent.
45. Upon information and belief, Alkem's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '601 patent.
46. Upon information and belief, Alkem will, through the manufacture, use, import, offer for sale, and/or sale of Alkem's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.
47. If Alkem's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '601 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI AGAINST ALKEM

Declaratory Judgment of Infringement of the '601 Patent

48. Paragraphs 1–47 are incorporated herein as set forth above.
49. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
50. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States

Constitution, and this actual case or controversy requires a declaration of rights by this Court.

51. Alkem has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Alkem's generic efinaconazole topical solution before the expiration date of the '601 patent, including Alkem's filing of ANDA No. 212195.

52. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's generic efinaconazole topical solution will constitute infringement of at least one claim of the '601 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Alkem on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '640 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '640 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '875 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale

in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '875 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Alkem has infringed at least one claim of the '601 patent by submitting or causing to be submitted ANDA No. 212195 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's generic efinaconazole topical solution before the expiration of the '601 patent;

4. order that the effective date of any approval by the FDA of Alkem's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

5. enjoin Alkem from the commercial manufacture, use, import, offer for sale, and/or sale of Alkem's generic efinaconazole topical solution until expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

6. enjoin Alkem and all persons acting in concert with Alkem from seeking, obtaining, or maintaining approval of Alkem's ANDA No. 212195 until expiration of the '640 patent, the '875 patent, and the '601 patent;

7. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

8. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: March 12, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: March 12, 2020
Newark, New Jersey

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